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10/725,629	12/01/2003	Pierre Beauparlant	9988-012-999	4706
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JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			BALASUBRAMANIAN, VENKATARAMAN	
			ART UNIT	PAPER NUMBER

1624

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/725,629

Applicant(s)

BEAUPARLANT ET AL.

Examiner

Venkataraman Balasubramanian

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-103 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-103 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/23/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group VII, claims 1-103, drawn to compounds of formula I, II, III, IV, wherein A, B, D, E are CR<sub>3</sub>, CR<sub>4</sub>, CR<sub>5</sub>, CR<sub>6</sub> respectively in the reply filed on 10/12/2005 is acknowledged. Claims 1-103 will be examined to the extent they embrace the elected subject matter. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-103 are pending.

### ***Information Disclosure Statement***

References cited in the Information Disclosure Statement, filed on 6/23/2005, are made of record.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 11-65 are rejected under U.S.C. 112, first paragraph, because the specification while being enabling for treating human lung cancer does not reasonably provide enablement for treating and or preventing any or all cancers or neoplastic diseases generically embraced in the claim language. The specification does not enable any physician skilled in the art of medicine, to use the invention commensurate in scope with these claims.

The instant method of use claims 11-65 are Reach through Claims. Reach through claims, in general have a format drawn to mechanistic, receptor binding or enzymatic functionality and thereby reach through any or all diseases, disorders or conditions for which they lack written description and enabling disclosure in the specification.

In the instant case, it appears that, because the instant compounds inhibit cell growth and imparts cytotoxicity, it is implied that, based on growth inhibition and or cytotoxicity, any or all cancer can be treated with the instant compounds for which there is no adequate written description and enabling disclosure. Besides the generic cancer, specification and claims also recite a list of preferred cancers for which also there is no enabling disclosure. Especially, above claims define the scope of the term cancer or neoplastic disease as 'wherein the cancer or neoplastic disease is leukemia, acute leukemia, acute lymphocytic leukemia, acute myelocytic leukemia, myeloblastic leukemia, Promyelocytic leukemia, myelomonocytic leukemia, monocytic leukemia, erythroleukemia, chronic leukemia, chronic myelocytic (granulocytic) leukemia, chronic lymphocytic leukemia, Polycythemia vera, Lymphoma, Hodgkin's disease, non-

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Hodgkin's disease, Multiple myeloma, Waldenström's macroglobulinemia, Heavy chain disease, fibrosarcoma, myxosarcoma, liposarcoma, chondrosarcoma, osteogenic sarcoma, chordoma, angiosarcoma, endotheliosarcoma, lymphangiosarcoma, lymphangioendotheliosarcoma, synovioma, mesothelioma, Ewing's tumor, leiomyosarcoma, rhabdomyosarcoma, colon carcinoma, pancreatic cancer, breast cancer, ovarian cancer, prostate cancer, squamous cell carcinoma, basal cell carcinoma, adenocarcinoma, sweat gland carcinoma, sebaceous gland carcinoma, papillary carcinoma, papillary adenocarcinomas, Cystadenocarcinoma, medullary carcinoma, bronchogenic carcinoma, renal cell carcinoma, hepatoma, bile duct carcinoma, choriocarcinoma, seminoma, embryonal carcinoma, Wilms' tumor, cervical cancer, uterine cancer, testicular tumor, lung carcinoma, small cell lung carcinoma, bladder carcinoma, epithelial carcinoma, glioma, astrocytoma, medulloblastoma, craniopharyngioma, ependymoma, pinealoma, hemangioblastoma, acoustic neuroma, oligodendroglioma, meningioma, melanoma, neuroblastoma, retinoblastoma, NSCL-LC carcinoma, NSCL-adrenocarcinoma, Liver cancer, Breast epithelial cancer, Endothelial cancer or 'Bronchial epithelial cancer', which are not adequately enabled solely based on the activity of the compounds provided in the specification. The instant compounds are disclosed to have cytotoxic activity and it is recited that the instant compounds are therefore useful in treating any or all cancer stated above for which applicants provide no competent evidence. It appears that the applicants are asserting that the embraced compounds because of their mode action as cytotoxic agents as tested in some specific cell lines that would be useful for all sorts of cancers. However, the applicants have not

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provided any competent evidence that the instantly disclosed tests are highly predictive for all the uses disclosed and embraced by the claim language for the intended host. Moreover many if not most of cancers, such as brain cancer, pancreatic cancer, colon cancer etc. are very difficult to treat and despite the fact that there are many anticancer drugs. Furthermore, scope of the claims also includes "prevention".

"To prevent" actually means *to anticipate or counter in advance, to keep from happening etc.* (as per Webster's II Dictionary) and there is no disclosure as to how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds can be administered in order to have the "prevention" effect. There is no evidence of record which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the cancer in general or those specifically claimed herein. The fact that specification recites combination therapy with various known anti-cancer agents clearly negate "prevention" of cancer by instant compounds.

Cancer would include benign tumors, malignant tumors, polyps, lumps, lesions, other pre-cancerous conditions, psoriasis, leukemia, the hyper proliferation of the gastric epithelium caused by the *Helicobacter pylori* infection of ulcers.

Cancer is just an umbrella term. Tumors vary from those so benign that they are never treated to those so virulent that all present therapy is useless.

No compound has ever been found to treat cancers of all types generally. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. The existence of such a "compound" is contrary to

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our present understanding of oncology. Cecil Textbook of Medicine states, "each specific type has unique biologic and clinical features that must be appreciated for proper diagnosis, treatment and study" (see the enclosed article, page 1004). Different types of cancers affect different organs and have different methods of growth and harm to the body. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally. Note substantiation of utility and its scope is required when utility is "speculative", "sufficiently unusual" or not provided. See *Ex parte Jovanovic*, 211 USPQ 907, 909; *In re Langer* 183 USPQ 288. Also note *Hoffman v. Klaus* 9 USPQ 2d 1657 and *Ex parte Powers* 220 USPQ 925 regarding type of testing needed to support in vivo uses.

Next, applicant's attention is drawn to the Revised Utility and Written Description Guidelines, at 66 FR 1092-1099, 2001 wherein it is emphasized that 'a claimed invention must have a specific and substantial utility'. The disclosure in the instant case is not sufficient to enable the instantly claimed method of treating or preventing solely based on the inhibitory activity disclosed for the compounds. The state of the art is indicative of the requirement for undue experimentation. Note instant diterpenoids are not taught in the prior art. Analogous art search was therefore made. See *Slamenova et al.*, *Basic Clin. Pharmacol. Toxicol.* 94(6): 282-290, 2004, wherein diterpenoid quinines, which showed cytotoxicity and apoptosis, was not found to be effective. Thus, mere cytotoxicity of a compound does not lead to anti-cancer agent without further studies. Specification lacks such showing.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

1) The nature of the invention: Therapeutic use of the compounds in treating or preventing cancer that require cytotoxic activity.

2) The state of the prior art: Recent publication expressed that the cytotoxicity effects by structurally related compound diterpenoid are unpredictable and are still exploratory. See Slamenova et al., cited above.

3) The predictability or lack thereof in the art: Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use for treating and preventing any or all cancers of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

4) The amount of direction or guidance present and 5) the presence or absence of working examples: Specification has no working examples to show treating and or preventing any or all cancers and the state of the art is that the effects of said cytotoxic agents are unpredictable.



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6) The breadth of the claims: The instant claims embrace treating and preventing any or all cancers and cancers including those yet to be amenable to said mode of action

7) The quantity of experimentation needed would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan, regarding the pharmaceutical use, for the reasons stated above.

Thus, factors such as “sufficient working examples”, “the level of skill in the art” and “predictability”, etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention, the unpredictability of enzyme-inhibitor interactions in general, and the lack of working examples regarding the activity of the claimed compounds towards treating and preventing the variety of cancer and neoplastic diseases of the instant claims, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

MPEP 2164.01(a) states, “A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).” That conclusion is clearly justified here. Thus, undue experimentation will be required to make Applicants’ invention.

Claims 72-103 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating fungal infection caused by *Sachromyces* and *Candida*, does not reasonably provide enablement for treating and or preventing any or all fungal infection generically embraced in claims 72-89 including those specifically recited in claims 90-103. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Following reasons apply.

The instant method of use claims 72-103 are drawn to "treating or preventing fungal infection". The scope of the claims includes treating or preventing any or all fungal infections in general for which there is no enabling disclosure. As recited these method of use claims are Reach through Claims. Reach through claims, in general have a format drawn to mechanistic, receptor binding or enzymatic functionality and thereby reach through any or all diseases, disorders or conditions for which they lack written description and enabling disclosure in the specification.

In the instant case, it appears that, because the instant compounds inhibit fungal growth, it is recited that, based on growth inhibition, any or all fungal infection can be treated with the instant compounds for which there is no adequate written description and enabling disclosure. Besides the generic fungal infection, specification and claims also recite a list of preferred fungal infections for which also there is no enabling disclosure. Especially, claims 90-103 define the scope of the fungal infection disease as 'wherein the fungus is *Candida*, *Aspergillus*, *Cryptococcus*, *Histoplasma*, *Coccidioides*, *Paracoccidioides*, *Blastomyces*, *Basidiobolus*, *Conidiobolus*, *Rhizopus*, *Rhizomucor*,

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Mucor, Asbidia, Mortierella, Cunninghamella, Saksenaea, Pseudallescheria, Paecilomyces, Fusarium, Trichophyton, Trichosporon, Microsporum, Epidermophyton, Scytalidium, Malassezia, Actinomycetes, Sporothrix, Penicillium, Saccharomyces, Pneumocystis or Scopulariopsis'.

However, specification provides no enabling disclosure showing that all these fungal infections can be treated and or prevented with use of the instant compounds.

"To prevent" actually means *to anticipate or counter in advance, to keep from happening etc.* (as per Webster's II Dictionary) and there is no disclosure as to how one skilled in the art can reasonably establish the basis and the type of subject to which the instant compounds can be administered in order to have the "prevention" effect. There is no evidence of record which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the fungal infection in general or those specifically claimed herein. Moreover many if not most of fungal infections such etc. are very difficult to treat and at present there is no known drug, which can successfully reverse the course of these infectious diseases, despite the fact that there are many antifungal drugs, which can be used for "treating fungal infections". No compound has ever been found to treat of all fungal infections generally.

Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. Note substantiation of utility and its scope is required when utility is "speculative", "sufficiently unusual" or not provided. See *Ex parte Jovanovics*, 211 USPQ 907, 909; *In re Langer* 183 USPQ 288. Also note

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Hoffman v. Klaus 9 USPQ 2d 1657 and Ex parte Powers 220 USPQ 925 regarding type of testing needed to support in vivo uses.

Next, applicant's attention is drawn to the Revised Interim Utility and Written Description Guidelines, at 64 FR 71427 and 71440 (December 21, 1999) wherein it is emphasized that 'a claimed invention must have a specific and substantial utility'. The disclosure in the instant case is not sufficient to enable the instantly claimed method of preventing solely based on the inhibitory activity disclosed for the compounds. The state of the art is indicative of the requirement for undue experimentation. See for example the two non-patent literature Turner et al., Current Pharmaceutical Design. 2, 209-224, 1996. and Sugar et al., Diagn. Microbiol. Infect. Dis. 21: 129-133, 1995. provided. Both these references suggest the art is still exploratory and that a single agent may not be able function as antifungal agents for all fungal infection, despite the fact that large number of antifungal agents were known.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

1) The nature of the invention: Therapeutic use of the compounds in treating and or preventing any or all fungal infections that require inhibiting activity of instant compound.

2) The state of the prior art: Although there are large number antifungal agents, none of them are claimed or shown to be useful in treating or preventing any or all fungal infections. Recent publications expressed that treating or preventing any or all fungal infection is still exploratory. See Turner et al. and Sugar et al., cited above.

3) The predictability or lack thereof in the art: Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds for treating and or preventing any or all fungal infections. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

4) The amount of direction or guidance present and 5) the presence or absence of working examples: Specification has no working examples for treating and or preventing any or all fungal infections and the state of the art is that the effects of fungal agents based on the disclosed inhibitory activity are unpredictable and at best limited to treating bacterial infections.

6) The breadth of the claims: The instant claims embrace any or all fungal infections.

7) The quantity of experimentation needed would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan, regarding the pharmaceutical use, for the reasons stated above.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant

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case for the instant method claims. In view of the breadth of the claims, the chemical nature of the invention, the unpredictability of receptor-ligand interactions in general, and the lack of working examples regarding the activity of the claimed compounds towards preventing and treating variety of fungal infections of the instant claims, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here. Thus, undue experimentation will be required to make Applicants' invention.

Claims 11-65 and 72-103 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for in vitro and vivo testing for lung cancer and for testing for fungal infection caused by *Sachromyces* and *Candida*, does not reasonably provide enablement for in vitro and in vivo testing for treating and or preventing any or all cancer and any or all fungal infection generically embraced in claims 11-39, 59-65, 72-89 including those specifically recited in claims 41-58 and 90-103 . The specification does not enable any person skilled in the art to which it pertains,

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or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Following reasons apply.

Representative examples of structurally diverse compounds generically embraced in the invention are not shown to possess in vitro activity much less in vivo uses claimed herein. Instant genus of diterpenoid embraces compounds with substituents bearing plethora of structural cores and functional groups and other groups permitted at instant  $R^1$  and  $R^2$  variables which include variously substituted monocyclic rings, bicyclic rings, tricyclic rings, spiro with variable ring sizes and variable heteroatoms, variety of reactive functional groups such COOH, OH, SH, amido, sulfoxides, sulfones nitrile, carbamates etc. There is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same bioactivity profile since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive art such as the pharmaceuticals.

Note Ex parte Gelles 22 USPQ 2nd 1318, especially the following quote: " The evidence relied upon also should be reasonably commensurate in scope with the subject matter claimed and illustrate the claimed subject matter " as a class" relative to prior art subject matter."

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant

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case for the instant method of use. In view of the breadth of the claims, the chemical nature of the invention, the unpredictability of enzyme-inhibitor interactions in general, and the lack of working examples regarding the activity of the claimed compounds towards treating and preventing the variety of diseases of the instant claims, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-103 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-66 of copending Application No. 10865,262. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds I, II, III, IV,



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their composition and method of use embraced in the instant claims overlap with compounds Ia, IIa, IIIa and IVa, their composition and method of use of copending application 10/865,262.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Conclusion**

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

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